F2F Human Participant Research Study Sunrise Plan

Study Narrative
Use to share study details and COVID protections with your Associate Dean for Research (or designee)

Section A: General Information about study and Principal Investigator(s)

1. School: School of Public Health (SPH)
2. Division/Center/Institute: Division of Epidemiology & Community Health
3. Study name (short name): Beverages and Diabetes (aka the SODAS Study)
4. Contact PI name: Mark Pereira
5. Contact PI Email: perei004@umn.edu
6. Other PI names ("NA" if not applicable): Andrew Odegaard, UC Irvine
7. Funding source ("unfunded" if so): NIH NIDDK
8. Study IRB number ("NA" if not applicable): STUDY00005127

Note: ALL sections of this form must conform to the study's approved IRB application, if applicable. No modifications are permissible without prior IRB approval.

Section B: Study Description

9. Describe your study in simple terms. What is the goal? Who are the research participants? What is the intervention, if any? When was this study's start date? When is the expected end date for field/in-person research? What measurements are taken, when, and what are the measurement intervals if applicable? [You may use text from study abstract, if applicable]

The primary goal of the study is to compare the effect of water to diet beverage consumption on glycemic control in otherwise healthy individuals with Type 2 Diabetes over 24 weeks. Secondary goals of the study include the comparison of water to diet beverage consumption on changes, if any, over 24 weeks in: a) the nature and magnitude of glycemic excursions as measured by a blinded continuous glucose monitor; b) cardiometabolic risk factors and kidney function; c) the overall habitual diet quality as assessed by multiple 24-hour dietary recalls during the trial; and d) appetite and sweet taste preferences. The study is also collecting fecal samples at baseline, 12 weeks, and 24 weeks and a second grant will be obtained to determine the impact of the two study conditions on gut microbiome.

The intervention is the random assignment to one of two study conditions: the daily consumption of 24 fluid ounces of either water or the diet (i.e. artificially sweetened) beverage of the participant’s choice. These beverages are delivered to the study participant on a monthly basis via Amazon or Instacart.
This two site study (primary site = UC Irvine) started in August 2019, with rolling recruitment. We are hoping to be done enrolling by early 2022, with all in-person visits ending 6-months later.

Each site is aiming to recruit 100 individuals; UMN currently has 18 completed or active participants.

The following measures are obtained at these time intervals:

- Week -2: Consent, and Provision of CGM, activPAL activity monitor, and Baseline fecal kit (aka “Run-in” Visit)
- Week 0: Blood pressure, weight, fasting urine, fasting blood draw, surveys (aka Baseline visit; Milestone visit)
- Week 6: Blood pressure, weight, fasting blood draw, surveys
- Week 10: Provision of CGM, activPAL activity monitor, and Week 12 fecal kit
- Week 12: Blood pressure, weight, fasting urine, fasting blood draw, surveys (Milestone visit)
- Week 18: Blood pressure, weight, fasting blood draw, surveys
- Week 22: Provision of CGM, activPAL activity monitor, and Week 24 fecal kit
- Week 24: Blood pressure, weight, fasting urine, fasting blood draw, surveys (Milestone visit)

10. Who are the researchers who will be involved in F2F participant interactions? Has each researcher considered the risks of this research to themselves and their social contacts, especially in light of each researcher’s own COVID risk profile and the work they will be assigned? What is the background/training of each researcher with respect to infection control and COVID prevention? What training has each research had in terms of proper use of PPE (e.g., mask donning and doffing, hand washing, hand sanitizer)? – See SPH PI Research Restart Toolkit for Resources

NOTE: UMN policy prohibits coercion or use of other measure of pressure to force participation of any individuals in order to resume F2F research activities.

Researchers involved in F2F interactions include:

Sarah Rydell (study coordinator)
Kristina Kuduk (phlebotomist)
Erika Swant (research assistant)

Each researcher has considered the risks of this research to themselves and their social contacts, and each person has agreed that they feel comfortable to resume F2F visits, especially given the safety measures taken by the study.

Ms. Kuduk is an experienced phlebotomist and has been trained extensively in infection control as part of her lab duties. Ms. Rydell and Ms. Swant have completed a variety of lab trainings that have included aspects of infection control.

More specific to COVID-19, all staff completed the UMN’s Coronavirus (COVID-19) Awareness training module and reviewed all of the applicable content on this page: https://www.uhs.umn.edu/uhs-covid-19-response-resources (i.e. PPE, Cloth Masks, Cleaning, COVID Guidance for the Research Community). Additionally, everyone completed the NIEHS COVID-19 Response Training available here: https://niehstraining.vividlms.com/
Ms. Rydell, the study coordinator, will ensure, via an online practice zoom meeting that all research staff know how to don and doff PPE appropriately and know the steps for proper handwashing. She will also stay up to date on any new developments in SARS-CoV-2 and COVID-19 risk factors via OVPR communications, ECRC Coordinators meetings, and reviewing primary sources. Any updated guidance will immediately be communicated to research staff.

11. Explain why face-to-face (F2F) interaction is necessary for this research. Why can't the study be done without F2F interaction? Be specific.

The study requires biological samples to be collected at distinct time intervals. While nearly all measures can be collected in a physically distanced manner, we are unable to collect fasting blood draws or blood pressure without F2F interaction.

Please note: Nearly all COVID-related modifications made to the study will remain in place when our study is able to resume F2F data collection (e.g. surveys will still be done remotely, participants will be provided with their week 10/22 monitors and fecal kit in a physically distanced manner, etc).

12. Describe the participants of this study. What is the age distribution? Do any participants or their social contacts have an elevated risk for COVID due to diabetes, high blood pressure, asthma, COPD, smoking, etc.? Are there other vulnerabilities (e.g., diminished capacity, educational attainment, low income) that merit consideration? Are there participants who were enrolled prior to the COVID-19 pause and who will be invited to resume participation? Be specific and use data if possible.

Participants are otherwise healthy individuals with Type 2 Diabetes aged 35 and older with a BMI of at least 20. The oldest person currently enrolled in the study is aged 65 years.

To ensure that these participants are otherwise healthy, the exclusion criteria for this study are as follows:

- Type 1 diabetes or suspected type 1 diabetes (lean with polyuria, polydipsia, and weight loss with little response to metformin)
- “Secondary” diabetes due to specific causes (e.g. monogenic syndromes, pancreatic surgery, and pancreatitis)
- Diabetic Ketoacidosis hospitalization within last 6 months
- Severe/major hypoglycemia in the last 3 months (severe/major hypoglycemia is defined as a hypoglycemic event in which patient requires assistance of another person to manage the episode)
- Glucocorticoid use (prednisone 2.5 mg/d or more or its equivalent)
- History of intolerance or allergy to diet beverages or AS or phenylketonuria
- Any condition that is known to affect the validity of the glycemic measures (HbA1c)
- Major cardiovascular disease event or surgery within the past 6 months
- Gastrointestinal, Renal or liver disease
- Current treatment for cancer
- Those with major surgery planned or history of bariatric surgery
- Antibiotic treatment (> 6 days) within past 6 months
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- Currently pregnant, planning to become pregnant during the study period, or if recently pregnant with < 1 year postpartum and breastfeeding
- Current participation in another interventional clinical trial
- Previous randomization in this study
- Heavy alcohol consumption (on average >1 drinks/day for women & >2 drinks/day for men)
- Habitual consumer of SSB ≥ 1 serving/day (8 oz.)
- Does not drink diet beverages
- Non-Smoker
- BMI < 20.0 kg/m2

No other vulnerabilities exist that merit consideration.

We have 7 people who enrolled prior to the COVID-19 pause who still need to provide their final fasting blood draw. Six of these individuals completed the 24-week trial with the COVID-modifications in place, and have agreed to continue with the intervention until we are able to collect the final blood draw. The seventh person will reach week 24 near the end of August 2020.

All of these people were given the option to discontinue the study when COVID-19 restrictions were implemented (no one wanted to stop) and again at each of their visits until their final visit at week 24, but all expressed the desire to continue until all measures were collected.

13. Where exactly will face-to-face research interactions take place? Classroom, computer lab, community center, home, outdoors? Describe all such settings/environments. Be precise and specific. (Note: If clinic or ECRC, go to question 15)

All F2F interactions will take place either outdoors or at the ECRC.

**Weeks -2, 0, 6, 12, 18, and 24:**
We anticipate the total time spent in the ECRC for these visits to be 15-20 minutes at maximum. Blood pressure & weight measures will take place in our study room at the ECRC. Fasting urine (collected at the three milestone visits) will be collected in the ECRC’s participant bathroom and brought by the participant to the lab. Blood draws will be collected in the ECRC’s lab.

**Weeks 10 & 22:**
Weather permitting, all materials provided at the week 10 and week 22 visit will be given outside the ECRC at the benches near the entrance, at Gold Medal park, or at a location of the participant’s choosing. If the weather doesn’t cooperate, these short (less than 10 minutes) visits will take place within our study room at the ECRC.

The study obtained a HEPA air-filtering unit that will be placed within our study room at the ECRC. (for reference, it was this one: https://www.amazon.com/dp/B00BTKAPUU/?tag=thewire06-20&linkCode=xm2&ascsubtag=AwEAAAAAAAAAAcps)
14. Answer this question if the research will take place at a location owned/managed by someone other than UMN (e.g., community group, YMCA, business). Who owns/manages the location? What is the owner/manager’s contact information? Has the owner/manager had training in infection control and/or COVID prevention? If so, describe. Is the location "open for business" for other activities or just this study? Are location owners/managers prepared for and willing to support this research study and take steps to prevent transmission of the new coronavirus? Explain.

NA

15. Answer this question if the research will take place in a clinical setting or involve any health system/M Health Fairview resources or services (e.g. international clinic/hospital, investigational drug pharmacy, imaging, lab, interventional radiology, ECRC, etc.). Provide a description of any health system/M Health Fairview resources or services needed (e.g. investigational drug pharmacy, imaging, lab, interventional radiology, etc). Will study team members need to be physically present within an M Health Fairview facility? If yes, what facility(ies)? If ECRC facilities will be used, you must comply with the ECRC requirements/ Sunset plan (https://drive.google.com/file/d/1WJOlm4I32mPmdZ6y6fhi7VJuvs0VMI1t/view?usp=sharing)

Study team members will be physically present at the ECRC. Either the study coordinator or research assistant will be collecting the blood pressure and weight measures, and the study phlebotomist will be receiving the fasting urine and collecting the fasting blood draws.

All staff will comply with the ECRC’s requirements and sunrise plan. In fact, Ms. Rydell has been actively involved with the development of some of these requirements.

Section C: Mitigating Participant Risk

16. Describe any situations where researchers will not be able to maintain at least 6 ft between themselves and participants in the research setting. Describe any situations in which anyone in the research setting will not be able to maintain at least 6 ft distance.

While in the study room, Ms. Rydell or Ms. Swant will be unable to maintain a distance of 6-feet when placing the blood pressure cuff on the participant’s arm in advance of the blood pressure measures. This process takes about 15 seconds. Otherwise, a minimum distance of 6 feet will be maintained.
Ms. Kuduk will be unable to maintain a distance of 6-feet when collecting the fasting blood draw. In the past, this process has taken her 2-3 minutes at most.

17. List the steps for research staff to self-assess their health status (e.g., body temperature, other symptoms) before F2F interactions with participants or other researchers.

Prior to any F2F interaction, all research staff will self-assess their health status by:
- Taking their temperature and ensure it is less than 100°F
- Ensure they have no loss of taste or smell by smelling and tasting a food in their home.
- Ensuring they have no currently known COVID-related symptoms as detailed in the OVPR’s COVID-19 Guidance for the Research Community.
- Ensure they have had no known contact with anyone known or suspected to have COVID-19.

18. Describe procedures for study participants to self-assess their health status (e.g., body temperature, other symptoms) before F2F interactions with researchers or other study participants. Describe how the research team will screen participants upon arriving at F2F research interaction.

At least 24 hours prior to any F2F visit, study participants will be provided with the Research Participation Information Sheet that emphasizes and reminds participants that all participation is voluntary. This information sheet will either be emailed or mailed via USPS (per participant request). The day prior to any F2F visit, study participants will be asked to assess their body temperature and answer a list of questions pertaining to COVID-19 symptoms and exposures (i.e. the ECRC pre-visit questionnaire). They will also be asked to bring/wear a mask to their visit.

Upon arrival at the ECRC for their F2F visit, participants will be provided with a mask if they are not wearing one already and be directed to the “Screening Room.” In that room, they will have their temperature checked and again asked the list of questions pertaining to COVID-19 symptoms and exposures (i.e. the ECRC COVID-19 upon arrival questionnaire).

Provided the participant passes both of these checks, the F2F visit will proceed.

19. Describe any electronic scheduling/calendaring/consent mechanisms to minimize F2F contact among people within the research setting. Note, F2F interactions should be minimized.

The ECRC utilizes the CTSI scheduling system and a resource entitled “Screening Room” has been added. Any participant to be seen at the ECRC will need to be scheduled in this room, which will serve to limit capacity within the ECRC. As of now, only one person can be scheduled per hour (though this may be modified to one person every 30 or 45 minutes at most), which will dramatically minimize the numbers of individuals within the ECRC at any one time. Given this limitation, the buffer time between individuals in our study room or the ECRC lab will be at minimum 30 minutes, and likely longer.
Additionally, if our past history of visits is any guide, we generally saw only one SODAS participant on the days that had study visits scheduled. The ECRC has also dramatically improved ventilation within the building and this time buffer will allow for appropriate air exchange.

With respect to study consents, we will be providing the study consent form via email in advance. When we call the participant to confirm their study visit, we will review the consent form over the phone. We can answer any remaining questions at the time of the in-person consent that takes place during the Run-In visit.

20. Describe use of PPE (e.g., masks, respirators, sanitizer) to mitigate risk. What will be used? How much is needed? What must be procured and by when? How will procurement and distribution for and within the study be conducted?

All study staff who will be interacting within 6 feet of any participants will use masks rated for low or no-splash/aerosol procedures (Level 1 or Level 2 masks); mask conservation methods, detailed below, will be employed. All study staff will also be provided with a face shield, should they wish to wear it (although face shields will be mandatory for the phlebotomist). The study phlebotomist will also wear gloves and a lab coat (laundered cloth lab coats preferred over disposable ones).

The study coordinator will distribute supplies to staff, as needed.

Mask Conservation Plan per consultation with UHS:
- Only one mask per day will be worn per person.
- Visibly soiled and/or damaged masks will be discarded.
- Masks may be used again, after slight use, but only by the same individual (i.e. masks will not be shared by study staff).
- If the level of supplies becomes critically low, the 1-5-5 plan will be implemented.

Level 2 masks, face shields, disinfectant wipes, and hand sanitizer have already been procured. Stock levels will be monitored, and will be re-ordered through UMarket.

21. Describe procedures to disinfect surfaces (e.g., tables, door handles, computers) before, between, and after interactions in the F2F research space. What cleaners/sanitizers will be used, by whom, and where will such items be procured?

All surfaces (e.g. table, top of scale, door handles, etc) will be cleaned before and after all participant F2F interactions by study staff listed in question 10. Cavi-wipes, disinfecting chlorox wipes, or disinfecting Lysol spray will be used, according to the label instructions.

These sanitizers will be purchased through UMarket or a commercial vendor such as Amazon or Target.
Section D: Mitigating Research Staff Risk

22. Describe procedures for research staff to self-assess their health status (e.g., body temperature, other symptoms) after F2F interactions with participants.

When F2F interactions resume, research staff will be asked to take their temperature daily, before and after study visits, ensure no loss of smell or taste, and watch for other symptoms of COVID-19 as detailed in the OVPR’s COVID-19 Guidance for the Research Community. They will also be vigilant in monitoring their in-person social networks in order to be cognizant of any known or probable exposures that would disqualify them from coming into work.

Good Health Habits will be employed in everyday life, including:
- Vigorously wash hands with soap and water for at least 20 seconds. Use hand sanitizer when soap washing is not possible.
- Cover your cough or sneeze with your elbow sleeve or other cloth. Wash hands immediately.
- Routinely clean all high-touch areas in your home and workplace.
- Do not touch your eyes, nose, or mouth with unwashed hands.
- Routinely sanitize phones, iPads, common printers, computers and all other such high-touch devices.
- Routinely sanitize desktops and all other high-touch surfaces.

If any worrying symptoms or exposures arise, Ms. Swant or Ms. Kuduk will call the study coordinator, while Ms. Rydell will notify the Study PI.

23. If applicable, describe how research staff will interact with each other or other employees? How will risk of COVID be mitigated in such settings?

All Staff will maintain a physical distance of at least 6 feet from other staff members and will wear a mask at all times. In-office time will be minimized to only being present for study visits and/or obtaining study materials.

Good health habits will be continued including vigorous hand washing for at least 20 seconds, or by using enough hand sanitizer, whereby skin is kept moist for a minimum of 15 seconds when washing is not possible, routinely sanitizing all high-touch services, and not touching eyes, nose, or mouth with unwashed hands.
Section D: PI Attestation of OVRP Research Sunrise

I confirm that I understand and will comply with any and all COVID mitigation requirements set forth by the University and the Office of the Vice President for Research.

I confirm that I understand and will comply with any and all COVID mitigation requirements set forth by my school’s Dean and/or Associate Dean for Research.

I confirm that I will quickly alert my Dean and/or Associate Dean for Research if there are any changes or adverse events to my study procedures or COVID mitigation plans.

I confirm that neither participants nor researchers will be pressured to engage in F2F research activities.

I understand that as conditions change, I may be required to alter or pause all face-to-face research interaction in this study.

Mark A. Pereira 8/11/20

Contact PI Signature Date

Other PI Signature Date

Other PI Signature Date

Other PI Signature Date

Associate Dean for Research Designee Signature Date

Note: typed signatures from UMN email account is acceptable]